(1 of 2)

K030123

AMERICAN MEDICAL SYSTEMS

510(k) SUMMARY

FEB 0 6 2003

Submitter's Name:	American Medical Systems, Inc.
Address:	10700 Bren Road West Minnetonka, MN 55343
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Contact Person:	David Worrell
Date of Summary Preparation:	January 13th, 2003
Device Common Name:	Surgical Mesh, Sling, Urethral Sling
Device Trade Name:	BioArc SP™ Sling Kit
Device Classification Name:	Surgical Mesh, polymeric
Predicate Device:	SPARC™ Sling System – K011251, K013355, K020663, K021263

Device Description

The BioArc SP Sling Kit is a sterile, single use procedure kit consisting of two stainless steel, 22cm curved needle passers (also called insertion tools) and two AMS Polypropylene sling Y-mesh. At one end of the sling Y-mesh, a clamp is attached by polypropylene suture to each leg of the "Y". The clamp is used for suturing a tissue graft to the sling Y-mesh. A dilating connector is attached to the opposite end of the sling Y-mesh. The dilating connector secures to the keyed end of the BioArc SP needle passer during the procedure to facilitate sling placement. A fixed polypropylene tensioning suture runs through the middle of each sling Y-mesh. A plastic sheath covers each sling Y-mesh and protects it during placement. The same suprapubic approach used to place the SPARC sling mesh is used to place the BioArc SP sling Y-mesh.

Indications for Use

The BioArc SP Sling Kit is intended for the placement of a pubourethral sling for the treatment of female stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

Comparison to Predicate Device

The fundamental scientific technology of the BioArc SP Y-mesh and needle passers is unchanged from the predicate device(s). The primary change to the device is the addition of the "Y" to one end of the sling mesh. The Y-end allows the physician to suture biologic graft material of their choice between the two pieces of 1.1cm x 22cm sling Y-mesh. The needle passers used with BioArc SP sling Y-mesh are the same as the ones used with SPARC sling mesh. BioArc SP sling Y-mesh uses the same suprapubic approach and surgical procedure for placement as the SPARC sling mesh.

Supporting Information

A risk analysis for the BioArc SP and the verification and validation activity reported in this Special 510(k) application substantiate equivalence to the predicate and did not raise any new questions of safety or effectiveness.

Conclusion

The BioArc SP Sling Kit is substantially equivalent to the predicate with respect to intended use, technological characteristics and performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. David Worrell
Sr. Regulatory Affairs Specialist
American Medical Systems, Inc.
10700 Bren Road West
MINNETONKA MN 55343

SEP 28 2003

Re: K030123
Trade/Device Name: BioArc SP™ Sling Kit
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: OTN
Dated: January 13, 2003
Received: January 14, 2003

Dear Mr. Worrell:

This letter corrects our substantially equivalent letter of February 6, 2003.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE ENCLOSURE

510(k) Number: K030123

Device Name: BioArc™ SP Sling Kit

Indications for Use: The BioArc™ SP Sling Kit is intended for the placement of a pubourethral sling for the treatment of female stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)
(Division Sign-off)
Division of General and Restorative Devices

510(k) Number _____

Prescription Use X OR Over the Counter Use_____
(Per 21 CFR801.109)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K030123